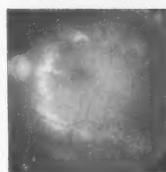


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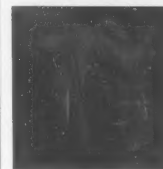
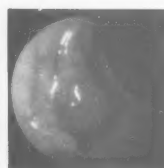
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Brief Summary

VERELAN® (Verapamil HCl) Sustained-Release Pellet Filled Capsules

For complete Prescribing Information, consult package insert.

CLINICAL PHARMACOLOGY

Antioventricular block can occur in patients without preexisting conduction defects (see **WARNINGS**). Acceleration of ventricular rate and/or ventricular fibrillation has been reported in patients with atrial flutter or atrial fibrillation and a coexisting accessory AV pathway following administration of verapamil (see **WARNINGS**). Food does not affect the extent or rate of the absorption of verapamil from the controlled-release VERELAN capsule. The bioequivalence of VERELAN 240 mg administered as the pellets sprinkled on applesauce and as the intact capsule, has been demonstrated. In patients with hepatic insufficiency, metabolism is delayed and elimination half-life prolonged up to 14 to 16 hours (see **PRECAUTIONS**); the volume of distribution is increased, and plasma clearance reduced to about 30% of normal.

CONTRAINDICATIONS

Severe LV dysfunction (see **WARNINGS**), hypotension (systolic pressure <90 mm Hg) or cardiogenic shock, sick sinus syndrome (if no functioning artificial ventricular pacemaker is present), second- or third-degree AV block (if no functioning artificial ventricular pacemaker is present), atrial flutter/fibrillation with an accessory bypass tract (eg, WPW LGL syndromes) (see **WARNINGS**), hypersensitivity to verapamil hydrochloride.

WARNINGS

Verapamil should be avoided in patients with severe LV dysfunction (eg, ejection fraction <30% or moderate to severe symptoms of cardiac failure) and in patients with any degree of ventricular dysfunction if they are receiving a beta-adrenergic blocker. Control of ventricular dysfunction with optimum digitalization and/or diuretics before VERELAN is used. Verapamil may occasionally produce hypotension. Elevations of liver enzymes have been reported. Several cases of hepatocellular injury have been demonstrated to be produced by verapamil. Periodic monitoring of liver function in patients on verapamil is prudent. Some patients with paroxysmal and/or chronic atrial flutter/fibrillation and an accessory AV pathway have developed increased antegrade conduction across the accessory pathway bypassing the AV node, producing a very rapid ventricular response or ventricular fibrillation after receiving IV verapamil (or digitalis). Because of this risk, oral verapamil is contraindicated in such patients. The effect of verapamil on AV conduction and the SA node may lead to asymptomatic first-degree AV block, transient bradycardia, and sometimes nodal escape rhythms. Higher degrees of AV block, however, were infrequently (0.6%) observed. Development of marked first-degree block or progression to second- or third-degree AV block requires reduction in dosage or, rarely, discontinuation of verapamil HCl and institution of appropriate therapy. Since bradycardia, second-degree AV block, sinus arrest, pulmonary edema and/or severe hypotension were seen in some critically ill patients with hypertrophic cardiomyopathy who were treated with verapamil.

PRECAUTIONS

THE CONTENTS OF THE VERELAN CAPSULE SHOULD NOT BE CRUSHED OR CHEWED. **General:** Verapamil should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of overdose. Verapamil may decrease neuromuscular transmission in patients with Duchenne's muscular dystrophy and may prolong recovery from the neuromuscular blocking agent vecuronium. It may be necessary to decrease verapamil dosage in patients with attenuated neuromuscular transmission. **Drug Interactions:** When the sprinkle method of administration is prescribed, the proper technique should be explained to the patient. (See **DOSE AND ADMINISTRATION** in full Prescribing Information.) Combined therapy with beta-adrenergic blockers and verapamil may result in additive negative effects on heart rate, antioventricular conduction and/or cardiac contractility. There have been reports of excess bradycardia and AV block, including complete heart block. For hypertensive patients, the risk of combined therapy may outweigh the benefits. The combination should be used only with caution and close monitoring. Decreased metoprolol clearance may occur with combined use. Chronic verapamil treatment can increase serum digoxin levels by 50% to 75% during the first week of therapy, which can result in digitalis toxicity. In patients with hepatic cirrhosis, the influence of verapamil on digoxin kinetics is magnified. Maintenance digoxin doses should be reduced when verapamil is given and the patient carefully monitored. Verapamil may usually have an additive effect in patients receiving blood pressure-lowering agents. Disopyramide should not be given within 48 hours before or 24 hours after verapamil administration. Concomitant use of fentanyl and verapamil may have additive effects on myocardial contractility, AV conduction, and repolarization. Combined verapamil and quinidine therapy in patients with hypertrophic cardiomyopathy should be avoided, since significant hypotension may result. Verapamil has been given concomitantly with short- and long-acting nitrates without any undesirable drug interactions. Interaction between cimetidine and chronically administered verapamil has not been studied. In healthy volunteers, clearance of verapamil was reduced or unchanged. Concomitant use of lithium and verapamil may result in a lowering of serum lithium levels or increased sensitivity to lithium. Patients receiving both drugs must be monitored carefully. Verapamil may increase carbamazepine concentrations during combined use. Rifampin may markedly reduce oral verapamil bioavailability. Phenobarbital may increase verapamil clearance. Verapamil may increase serum levels of cyclosporine. Concomitant use of inhalation anesthetics and calcium antagonists needs careful titration to avoid excessive cardiovascular depression. Verapamil may potentiate the activity of neuromuscular blocking agents (curare-like and depolarizing); dosage reduction may be required. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** One study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. **Pregnancy:** Category C. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. **Labor and Delivery:** It is not known whether verapamil use during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs labor, or increases the need for forceps delivery or other obstetric intervention. Such adverse experiences have not been reported despite a long history of verapamil HCl use in Europe for treatment of cardiac side effects of beta-adrenergic agonist agents used to treat premature labor. **Nursing Mothers:** Verapamil is excreted in breast milk; therefore, nursing should be discontinued during verapamil use. **Pediatric Use:** Safety and efficacy of verapamil in children below the age of 18 years have not been established.

ADVERSE REACTIONS

Reversible (upon discontinuation of verapamil) nonobstructive, paralytic ileus has been infrequently reported in association with the use of verapamil. In clinical trials with 285 hypertensive patients on VERELAN for more than 1 week, the following adverse reactions were reported in greater than 1% of patients: constipation (74%), headache (5.3%), dizziness (4.2%), lethargy (3.2%), dyspepsia (2.5%), rash (1.4%), ankle edema (1.4%), sleep disturbance (1.4%), myalgia (1.1%). In clinical trials of other formulations of verapamil HCl (N = 4,954), the following reactions have occurred at rates greater than 1.0%: constipation (73%), dizziness (3.3%), nausea (2.7%), hypotension (2.5%), edema (1.9%), headache (2.2%), rash (1.2%), CHF/pulmonary edema (1.1%), fatigue (1.7%), bradycardia (HR <50/min) (1.4%), AV block-total 1°, 2°, 3° (1.2%), 2° and 3° (0.8%), flushing (0.6%), elevated liver enzymes (see **WARNINGS**). The following reactions, reported in 1.0% or less of patients, occurred under conditions (open trials, marketing experience) where a causal relationship is uncertain. **Cardiovascular:** angina pectoris, antioventricular dissociation, chest pain, claudication, myocardial infarction, palpitations, purpura (vasculitis), syncope. **Digestive System:** diarrhea, dry mouth, gastrointestinal distress, gingival hyperplasia. **Hemic and Lymphatic:** ecchymosis or bruising. **Nervous System:** cerebrovascular accident, confusion, equilibrium disorders, insomnia, muscle cramps, paresthesia, psychotic symptoms, shakiness, somnolence. **Respiratory:** dyspnea. **Skin:** arthralgia and rash, exanthema, hives, hyperkeratosis, maculae, swelling, urticaria, Stevens-Johnson syndrome, erythema multiforme. **Special Senses:** blurred vision. **Urogenital:** gynecomaastia, impotence, increased urination, spotty menstruation.

OVERDOSAGE

Treatment should be supportive. Verapamil cannot be removed by hemodialysis. Clinically significant hypotensive reactions or high degree AV block should be treated with vasopressor agents or cardiac pacing, respectively.

DOSE AND ADMINISTRATION

VERELAN Pellet Filled Capsules may also be administered by carefully opening the capsule and sprinkling the pellets on a spoonful of applesauce. Please see full Prescribing Information for complete dosing and precautionary information.

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Manufactured for
Adventus Pharmaceuticals and
LEDERLE LABORATORIES DIVISION
American Cyanamid Company
Pearl River, NY 10965

ELAN PHARMA, INC.
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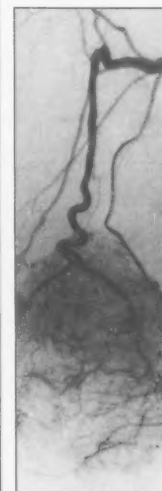
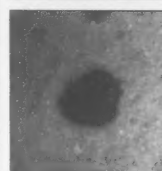
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